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10/574,003

09/29/2006

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EXAMINER

LE, NINH V

ART UNIT

PAPER NUMBER

1791

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/574,003 | <b>Applicant(s)</b><br>CURDY ET AL. |  |
|                              | <b>Examiner</b><br>Ninh V. Le        | <b>Art Unit</b><br>1791             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/29/06 and 5/11/09 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/6/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This is a final Office action in response to the response to a non-final Office action on 7/23/09.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 10/6/09 was filed after the mailing date of the non-final Office action on 7/23/09. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

#### ***Specification***

Objection to the specification has been withdrawn due to the Examiner's reconsideration. However, objection to the specification remains as follow.

The disclosure is objected to because of the following informalities: The Examiner acknowledges applicant's amendment to the specification for the heading "Brief Description of the Drawings", however, the disclosure still lacks a proper heading for "Background Of The Invention" and "Brief Summary Of The Invention". Please refer to the following guideline.

Appropriate correction is required.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in

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upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. **See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).** Correction of the following is required: The Examiner would like to note that the claim or claims must conform to the invention as set forth in the remainder of the specification and the **terms and phrases used in the claims must find clear support or antecedent basis in the description** so that the meaning of the terms in the claims may be ascertainable by reference to the description as set forth by 37 CFR 1.75 (d)(1). Additionally, the **meaning of every term used in any of the claims should be apparent from the descriptive portion of the specification with clear disclosure as to its import**; and

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in mechanical cases, it should be **identified in the descriptive portion of the specification** by reference to the drawing, designating the part or parts therein to which the term applies as set forth in MPEP § 608.01(o). Thus, the specification is being objected to because the following recitations in the corresponding claims do not have support in the written description of the disclosure.

In claim 1 line 4-6, “a homogenization compartment in the form of a cylinder which is defined by a tubular wall forming the casing of said cylinder and by a first side wall and a second side wall which are positioned at each end of said tubular wall” is not in the disclosure.

In claim 1 line 14, “a) said side walls are positioned along a vertical plane” is not the disclosure.

In claim 1 line 15, “b) the axis of symmetry of said cylinder is positioned horizontally” is not the disclosure.

In claim 1 line 16, “c) the rotor is installed so that it rotates about a horizontal axis which passes through said second side wall” is not the disclosure.

In claim 2 line 2, “wherein the rotor and the stator are cylindrical in shape” is not the disclosure.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2,4-7,13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. US Patent 5868973 (hereinafter Muller '973). Examiner wishes to point out to applicant that claims 1-2,4-7,13 are directed towards an apparatus and as such will be examined under such conditions. The material worked upon or the processes of using the apparatus are viewed as recitation of intended use and are given little patentable weight (Please see MPEP 2114 R1-2115 R2 for further details).

**Regarding claims 1-2,4-7,13, Muller '973 discloses as shown in Figures 2-3,** a device for the continuous manufacture of microparticles or nanoparticles from at least one aqueous phase and one organic phase comprising (Column 1 Line 5-23):  
a homogenization compartment (housing (41)) in the form of a cylinder (Figure 3 housing (41)) which is defined by a tubular wall (Figure 3 housing (41)) forming the casing of said cylinder (Figure 3 housing (41)) and by a first side wall (wall side of

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housing (41) where the dope supply line (3) enters) and a second side wall (wall side of housing (41) between sliding ring seal (64) and stator (45)) which are positioned at each end of said tubular wall (housing (41)); the device additionally comprising a first inlet (dope supply line (3)) and a second inlet (curved feed line (9)) which pass through said first side wall (wall side of housing (41) where the dope supply line (3) enters) and which are appropriate for respectively delivering an organic phase and an aqueous phase to the homogenization compartment (housing (41)) and an outlet (discharge pipe (13)) appropriate for extracting a particle suspension from the homogenization compartment (housing (41)); the homogenization compartment (housing (41)) including a mixing system comprising a rotor/stator combination (rotor (44) stator (45 and 43)), wherein

a) said side walls are positioned along a plane (wall side of housing (41) where the dope supply line (3) enters) and (wall side of housing (41) between sliding ring seal (64) and stator (45)),

b) the axis of symmetry of said cylinder is positioned in a plane (Figures 2-3 housing (41)),

c) the rotor is installed so that it rotates about an axis (rotor (44)) which passes through said second side wall (wall side of housing (41) between sliding ring seal (64) and stator (45)),

d) said first inlet is a hollow tube (dope supply line (3)) positioned in the extension of the axis of the rotor (rotor (44)) and comprises a tip (nozzle (46-49)) situated inside the rotor (rotor (44)) and inside the stator (stator (43 and 45)), and

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e) the homogenization compartment (housing (41)) exhibits a top side on which said outlet (discharge pipe (13); note: it is the Examiner's position that the discharge pipe (13) is situated at a top side) is situated.

Wherein the rotor (rotor (44)) and the stator (stator (43 and 45)) are cylindrical in shape (Note: the sprocket (50) is part of the rotor (44) assembly (Column 9 Line 52) therefore, the rotor also has a cylindrical shape like the sprocket (50) as shown in Figure 3.

Additionally, the stator (43) has a ring-shaped base plate (11) (Column 9 Line 60)).

Wherein the first inlet (dope supply line (3)) comprises perforations (nozzle (46-49)).

Wherein the number of perforations (nozzle (46-49)) is from 1 to 20 (nozzle (46-49)).

Wherein the perforations (nozzle (46-49)) have a diameter (nozzle diameter between 5 and 10 mm, Column 8 Line 1-2). Wherein the dimensions of the rotor/stator combination (rotor (44) stator (43 and 45)) are such that the mixing system (rotor (44) stator (43 and 45)) occupies a volume of the homogenization compartment (housing (41); note: The rotor (44) and stator (43 and 45) combination occupies more than 80% of the housing (41)). Wherein the rotor (rotor (44)) and the stator (stator (43 and 45)) comprise a row of teeth (teeth (55)) and have spacing between the teeth (teeth (55); Note: between each teeth (55) there are spacing created by the gap (54)).

Muller '973 discloses the claimed invention except for the side walls which are positioned along a vertical plane, the cylinder having an axis of symmetry that is horizontal, and the rotor rotating about a horizontal axis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the side walls positioned along a vertical plane, the cylinder having an axis of symmetry



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that is horizontal, and the rotor rotating about a horizontal axis, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

Additionally, Muller '973 discloses the claimed invention except for the perforations having a diameter from 0.01 mm to 1 mm, a mixing system that occupies 4% to 40% of the volume of the homogenization compartment, and the spacing between the teeth is from 1 to 4 mm. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the perforations to have a diameter from 0.01 mm to 1 mm, the mixing system to occupy 4% to 40% of the volume of the homogenization compartment and to have the spacing between the teeth to be from 1 to 4 mm for the intended application, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Response to Arguments***

Applicant's arguments filed 12/23/09 have been fully considered but they are not persuasive.

**Regarding claim 1, applicant argued** that Muller failed to teach a device for the continuous manufacture of microparticles or nanoparticles from at least one aqueous phase and one organic phase. Additionally, applicant alleged that Muller's inlet tubes are not suitable for the flow of an organic phase and an aqueous phase. Furthermore, applicant argued that Muller's device is teaching away from applicant's claimed

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invention because the sides of the Muller device are not vertical, the axis of symmetry of the cylinder is not horizontal, and the rotor does not move around a horizontal axis.

**The Examiner respectfully disagrees.** It is submitted that Muller teach an apparatus for producing fibrets having very fine fibers size in the range of below 1  $\mu\text{m}$  (Column 1 Line 5-23 and also see Column 8 Line 39-43) which reads on the recitation of “microparticles or nanoparticles” as claimed. Regarding the inlet tubes, Muller discloses a dope line (3) (Column 9 Line 12) comprising of an organic phase of cellulose esters or cellulose ethers (Column 5 Line 9-13) and a coagulation bath supply line (9) comprising of an aqueous phase of nonsolvent such as water (Column 9 Line 14-19), ethanol, and methanol (Column 5 Line 25-32). Additionally, in response to applicant's argument that Muller failed to teach manufacturing of microparticles or nanoparticles from at least one aqueous phase and one organic phase, it is submitted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Regarding applicant's argument in reference to the configuration of the device, it is submitted that Muller does not explicitly disclose a device that is vertical, the axis of symmetry of the cylinder is horizontal, and the rotor rotating about a horizontal axis.

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Also, although Muller discloses that the dispersing facility (40) is in vertical position as shown in Figure 2, nowhere in Muller's specification does he prohibit the rearrangement of the device to be horizontal. Thus, as demonstrated in the above rejection, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have the side walls positioned along a vertical plane, the cylinder having an axis of symmetry that is horizontal, and the rotor rotating about a horizontal axis, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. Note, in rearranging Muller's device, the entire dispersing facility (40) is configured exactly as shown in Figure 2 but the device would be rotated 90 degrees. Therefore, in this arrangement, the side walls would be positioned along a vertical plane, the cylinder would have an axis of symmetry that is horizontal, and the rotor would rotate about a horizontal axis as recited in the instant claim 1.

**Regarding applicant's dissent** with the objection to the specification, the Examiner would like to direct applicant to MPEP 608.01 (o) and 37 CFR 1.75(d)(1) for clarification.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ninh V. Le whose telephone number is (571)270-3828. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on (571)272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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NVL

/Joseph S. Del Sole/

Supervisory Patent Examiner, Art Unit 1791